

## CLAIMS

We claim:

1           1.       A method for controlling the rate of release of a biologically active protein  
2 comprising the step of adding the protein to a completely biodegradable blend of about 95 to 5%  
3 by weight of a homopolymer of  $\epsilon$ -caprolactone and about 5 to about 95% by weight of a  
4 crystallization modifier selected from the group consisting of crystalline fatty acids and  
5 crystalline esters of fatty acids which are saturated  $C_{12}$ - $C_{18}$  fatty acid esters of polyhydric  
6 alcohols.

1           2.       The method of claim 1 wherein the crystallization modifier is crystalline  
2 esters or fatty acids which are saturated  $C_{12}$ - $C_{18}$  fatty acid esters of polyhydric alcohols.

1           3.       The method of claim 2 wherein the polyhydric alcohols are selected from  
2 the group consisting of glycerol, ethylene glycol and propylene glycol.

1           4.       The method of claim 3 wherein the polyhydric alcohol is glycerol  
2 monostearate.

1           5.       The method of claim 1 wherein the protein is selected from the group  
2 consisting of enzyme, peptide and antibody.

1           6.       The method of claim 1 further comprising lyophilizing a solution  
2 containing the protein before adding the protein to the blend.

1           7.       The method of claim 1 wherein the protein is added in the amount ranging  
2 from about 1% to about 60 % by weight of the blend.

1           8.       The method of claim 7 wherein the protein is added in the amount  
2 ranging from about 10% to about 40% by weight of the blend.

1           9.     A method for controlling the rate of release of a biologically active protein  
2 comprising the step of adding the protein to a completely biodegradable blend of about 95 to 5%  
3 by weight of a copolymer of at least 80% by weight  $\epsilon$ -caprolactone and corresponding remainder  
4 weight of another absorbable monomer; and about 5 to about 95% by weight of a crystallization  
5 modifier selected from the group consisting of crystalline fatty acids and crystalline esters of  
6 fatty acids which are saturated C<sub>12</sub>-C<sub>18</sub> fatty acid esters of polyhydric alcohols.

1           10.    A completely biodegradable preparation providing extended release of a  
2 biologically active protein comprising an effective amount of the protein in a blend of about 95  
3 to 5% by weight of a homopolymer of  $\epsilon$ -caprolactone and about 5 to about 95% by weight of a  
4 crystallization modifier selected from the group consisting of crystalline fatty acids and  
5 crystalline esters of fatty acids which are saturated C<sub>12</sub>-C<sub>18</sub> fatty acid esters of polyhydric  
6 alcohols.

1           11.    The preparation of claim 10 wherein the protein is an enzyme.

1           12.    The preparation of claim 11 wherein the enzyme is alkaline phosphatase.

1           13.    The preparation of claim 10 wherein the protein is a peptide.

1           14.    The preparation of claim 13 wherein the peptide is leuprolide acetate.

1           15.    The preparation of claim 10 wherein the protein is an antibody.

1           16.    The preparation of claim 15 wherein the antibody is anti-EM.

1           17.    The preparation of claim 10 wherein the crystallization modifier is  
2 crystalline esters of fatty acids which are saturated C<sub>12</sub>-C<sub>18</sub> fatty acid esters of polyhydric  
3 alcohols.

1           18.    The preparation of claim 17 wherein the polyhydric alcohols are selected  
2 from the group consisting of glycerol, ethylene glycol and propylene glycol.

1                   19.    The preparation of claim 18 wherein the polyhydric alcohol is glycerol  
2 monostearate.

1                   20.    The preparation of claim 10 wherein the homopolymer of  $\epsilon$ -caprolactone  
2 is present in the amount ranging from about 70% to about 30% by weight of the blend and the  
3 crystallization modifier is present in the amount ranging from about 30% to about 70% by  
4 weight of the blend.

1                   21.    The preparation of claim 20 wherein the homopolymer of  $\epsilon$ -caprolactone  
2 and the crystallization modifier are each about 50% by weight of the blend.

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22.    A completely biodegradable preparation providing extended release of a  
biologically active protein comprising an effective amount of the protein in a blend of about 95  
to 5% by weight of a copolymer of at least 80% by weight of  $\epsilon$ -caprolactone and corresponding  
remainder weight of another absorbable monomer; and about 5 to about 95% by weight of a  
crystallization modifier selected from the group consisting of crystalline fatty acids and  
crystalline esters of fatty acids which are saturated  $C_{12}$ - $C_{18}$  fatty acid esters of polyhydric  
alcohols.